Enitra 8

Pacemaker

Patient Information

Prior to Implantation

Enitra 8

You have been diagnosed with a cardiac arrhythmia; the possible causes of such disturbances in one's heart rhythm can be many and various. It is possible that your heart is beating too slowly, too infrequently or too irregularly. A pacemaker is indicated for your illness if its symptoms can be eased by the use of such a device. The pacemaker is generally implanted under your collarbone and connected to the heart by means of leads. These leads are extremely thin electrically insulated wires that can detect your heart activity and pass that information back to the pacemaker. If the leads can detect no activity, the pacemaker emits electrical pulses, which are transmitted to the heart via the leads. These pulses stimulate the heart, which contracts, thus keeping your heart rhythm regular.

Depending on the illness with which you have been diagnosed, your pacemaker will need to stimulate either two or three chambers of your heart. For this reason, either two or three leads will be connected to your pacemaker. This patient information sheet contains information on the Enitra 8 DR-T implantable pacemaker (a dual-chamber pacemaker), as well as the Enitra 8 HF-T and Enitra 8 HF-T QP implantable pacemakers (both of which are triple-chamber pacemakers). After implantation you will be given a patient ID card. This card will contain information on the components actually implanted in your chest.

BIOTRONIK
excellence for life

The Enitra 8 supports implanted device monitoring using Home Monitoring. This allows your medical team to monitor the state of health of your heart and the condition of the implanted device continuously, and to identify any anomalies. The data from the pacemaker are transferred onto your transmitter, the CardioMessenger. The CardioMessenger then sends the encrypted information on to your physician.

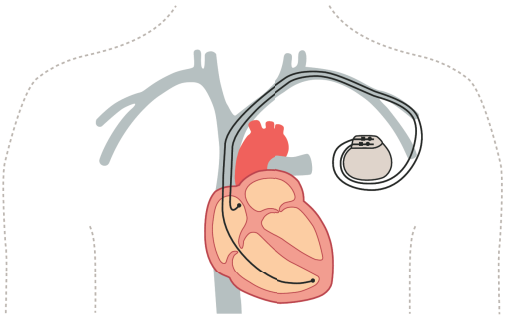

Fig. 1: Illustration of a dual-chamber pacemaker
The leads connect the pacemaker with your heart's right atrium and with its right ventricle.

Biocompatibility

The pacemaker contains the following substances that come into contact with your body:

- Titanium
- Plastics (epoxy resin, polysulfone, silastic, and silopren)

It should be said that it does not contain residues of any material that may pose a risk after implantation.

Please inform your physician if you are allergic to any of these substances.

After Implantation

Possible Complications

BIOTRONIK has taken steps to minimize any residual risk. However, the following complications may arise either during or after implantation of your pacemaker:

- Injury to cardiac tissues during implantation
- Accumulations of liquid in the device pocket
- Infections
- Tissue reaction
- Unintended stimulation of the diaphragm (causing hiccups)
- Allergic reactions to biocompatible materials

Your physician will decide on action to be taken if any complication should arise.

Information on How to Behave Directly after the Implantation

- Avoid expansive arm movements in the first few weeks after implantation.
- Ensure that the area of your post-operative scar is not disturbed.

Consult your physician if any of the following anomalies should occur:

- Blood or liquid is secreted by your post-operative scar.
- The post-operative wound swells up and becomes warm.
- The pain you feel after the implantation eases at first and then increases again.

General Behavioral Information for Implanted Patients

- Mobile metal detectors may interfere with your implanted device. Show your patient ID card and ask to be hand-searched. Briefly passing through permanently installed metal detectors will not interfere with your pacemaker.
- Avoid any work involving electrical welding or exposure to high voltages.
- Avoid any pressures above normal levels, such as those exposed to when scuba diving.
- Be careful to avoid any impact on your implanted device.
- Stay away from industrial plants that generate strong magnetic fields due to high-energy electrical currents.
- Avoid direct contact with electrical currents. In case you receive an electric shock, check that your implanted device is still functioning correctly.
- Carry your patient ID card with you at all times.
- Avoid areas marked with the following warning symbol: 
- Electrical devices create electromagnetic fields that may interfere with your implanted device. The implanted device is designed to be almost unaffected by electromagnetic fields, though it is impossible to be absolutely sure that it will not be affected. For this reason, maintain the following minimum distances between electrical devices and your implanted device:

Device or system	Minimum distance
Mobile phones or smartphones	15 cm
Cable-powered electrical tools	15 cm
Petrol-driven tools (e.g., chainsaws)	30 cm
Electronic anti-theft systems, as one finds, for example, at the cash desk in stores	30 cm
Powerful loudspeakers	30 cm
Electrical devices with powerful motors, such as lawn-mowers, car ignition systems, etc.	30 cm

Follow-up Care

Your physician will call you regularly or as needed for follow-ups. This follow-up is important to check the state of your implanted device, i.e., to check its remaining service time and that it is working properly. In addition, your physician can also decide on further treatment on the basis of these examinations.

Follow-up intervals

Follow-ups must be carried out at regular intervals. The follow-up intervals for you will be set individually by your physician as appropriate.

BIOTRONIK recommends the following intervals:

- The first follow-up by the physician (in-office follow-up) should take place once the leads are fully incorporated, about three months after implantation.
- In-office follow-ups should be carried out once a year, with a maximum interval of 12 months between each meeting.

Follow-up with BIOTRONIK Home Monitoring

The implanted device allows additional monitoring using the Home Monitoring system.
Your physician will decide whether the data provided by the Home Monitoring system are sufficient to make a judgment on your clinical status and on the condition of your device system. If the provided data is insufficient, an in-office follow-up must be carried out.
Get in touch with your physician if your symptoms should recur or deteriorate, even if you are using Home Monitoring.

Medical Examinations and Treatments

Show your patient ID card before undergoing any medical examination or treatment. Your medical specialists can evaluate whether your pacemaker is suitable for the examination and whether safety measures need to be taken when conducting your treatment.

The following procedures should be avoided:

- Therapeutic ultrasound
- Transcutaneous electrical nerve stimulation (i.e. stimulation through one's skin)
- Hyperbaric oxygen therapy (high-pressure chamber treatments)

Special precautions should be taken when using the following procedures:

- External defibrillation
- High-frequency surgical procedures such as electrocautery (obliteration of blood vessels) and high-frequency ablation (obliteration of tissue)
- Radiation therapy
- Magnetic resonance imaging

  While your pacemaker is approved for use in magnetic resonance imaging (MRI) scanners, a number of conditions must be adhered to. On the basis of the information on your patient ID, your physician can also assess whether the pacemaker's leads are suitable for the examination and can decide what precautions need to be taken.

Incidents

If the symptoms you had before implantation of the pacemaker should recur after your implantation, this may indicate a malfunction in your implanted device.

- Contact your physician if any of the following symptoms should occur:
  - Fatigue or loss of performance
  - Shortness of breath or dizziness
  - Fainting or near fainting
- If you should detect any anomaly or experience an incident with your implanted device, please inform:
  - Your physician
  - The manufacturer, BIOTRONIK (http://www.biotronik.com)
  - The Therapeutic Goods Administration (TGA) (https://www.tga.gov.au/)

Service Time

The service time of the implanted device cannot be determined as a general rule; it will depend on how much power the pacemaker needs to provide the therapy to your heart. A decisive factor in the calculation will be the number of heart chambers being stimulated. Other decisive factors include the power of the electrical pulses emitted, the duration of each individual pulse and the frequency at which they are triggered. During follow-ups, your physician will check the condition of the battery regularly and take any action that may be necessary.

The following mean service times apply:

Dual-chamber pacemakers

Pulse (amplitude)	Pacing	Average service time
2.5 V	100 %	9 years, 4 months
	50 %	11 years, 4 months
3.0 V	100 %	7 years, 8 months
	50 %	10 years
5.0 V	100 %	3 years, 2 months

Triple-chamber pacemakers

Pulse (amplitude)	Pacing	Average service time
2.5 V	100 %	9 years, 8 months
3.0 V	100 %	8 years
5.0 V	100 %	2 years, 6 months

Validity of this Patient Information Sheet

Please check regularly on the Internet for any updated editions of this information sheet at: www.biotronik.com/en-au/patients.

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin / Germany
Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6852804
sales@biotronik.com
www.biotronik.com

446497-A

BIOTRONIK
excellence for life